

**JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1**  
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements ***explaining the absence of competition*** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

**1. PURCHASE REQUEST OR REQUISITION NUMBER:**  
673-15-2-074-0609

**1A. PROJECT/TASK  
NUMBER**  
NONE

**1B. ESTIMATED AMOUNT:**  
\$48635.00

**2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:**

This request is to purchase Pressure Wire FFR Measurement System with Agile Tip from St. Jude. PressureWire Agile Tip, improved responsiveness and steerability for easy handling in difficult anatomies. The PressureWire Agile tip technology also includes a new proprietary hydrophilic coating to reduce friction; making it easier for doctors to deploy stents and coronary balloons.

**3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER**

Each FFR manufacture has custom connections (housing to catheter) that prevent other manufacturers products from being used. In the case of ACIST's FFR product, St Jude's is different in that it is not a pressure wire, like other manufacturers. St. Jude has a rapid exchange catheter based system that works with fiber optics (unlike others). There are no known products that could interface with St. Jude's FFR systems in the market place that could interchange with other catheters.

**4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:**

James A. Haley is currently using St. Jude's FFR system; this product is exclusive in its design and characteristic as well as being machine specific to the St Jude FFR System.

Currently St. Jude Medical markets their FFR system, along with an OCT high resolution imaging modality. FFR (Fractional Flow Reserve) is a functional measurement system, used to help determine whether stenting a blockage will provide benefit to the patient. The efficacy of FFR has been proven over many clinical trials such as FAME and FAME II. IVUS (IntraVascular UltraSound) is an imaging modality, which can be used to improve accuracy of stent placement and to assure that the stent has been expanded optimally (underexpansion of stents has been associated with increased restenosis).

Because, of the product's construction and inherent physical characteristics, competing products may not replace them without the possibility of causing additional complications during patient care. It is imperative that the products that could interface with St. Jude's FFR are purchase due to physicians need. Physicians are trained in the use of FFR from St. Jude, different or unfamiliar products can cause further complications and so placing patients at risk.

**5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:**

No market research was conducted due to the emergent nature of this procurement, normal procurement procedures is not possible. For future procurements, competition will be solicited if non-emergent in nature.

**6. Contracting Officer's Certification:** *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

**Signature:**

**Date:** \_04/0/62015

**Name:** Leonora Simmons

**Title:** Contract Specialist

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